

*REMARKS/ARGUMENTS**The Pending Claims*

Claims 1-17, 69, 70, and 78-85 are pending currently and are directed to a composition comprising particulate tricalcium phosphate (TCP) having an average particle size of about 5  $\mu\text{m}$  or less, an average crystal size of about 250 nm or less and a surface area of about 20  $\text{m}^2/\text{g}$  or greater. Reconsideration of the pending claims is respectfully requested.

*The Amendments to the Claims*

Claims 1, 69, 70 and 79 have been amended to eliminate “can be” language and to affirmatively recite that when the particulate TCP is densified it has the recited light transmittance, compressive strength and/or density properties.

New claims 80-85 have been added. New claims 80-82 are dependent on claim 1 and recite that the the particulate TCP is produced by a process that involves a wet chemical approach. New independent claim 83, as well as claims 84 and 85 dependent thereon, recite a composition comprising particulate tricalcium phosphate (TCP) having an average particle size of about 5  $\mu\text{m}$  or less, an average crystal size of about 250 nm or less and a surface area of about 20  $\text{m}^2/\text{g}$  or greater, wherein the particulate TCP is produced using a wet chemical approach, and wherein when the particulate TCP is densified to form an article having a minimum dimension of about 0.5 cm or greater the article has a density that is 90% of the theoretical density or greater. These claims are supported by the specification at, e.g., page 7, paragraph [0028], and page 8, paragraph [0030].

No new matter has been added by way of these amendments.

*Summary of the Office Action*

Claims 1-7, 12-14, 17 and 69-73 stand again rejected under 35 U.S.C. § 103(a) as obvious over Kawamura et al. (i.e., U.S. Patent 4,717,556) in view of Tanaka et al. (i.e., U.S. Patent 6,441,073). Claims 8-11 stand again rejected under 35 U.S.C. § 103(a) as obvious over Kawamura et al., Tanaka et al., and Kijima et al. (i.e., U.S. Patent 5,185,177). Claims 15 and 16 stand again rejected under 35 U.S.C. § 103(a) as obvious over Kawamura et al.,

Tanaka et al., and Dalal et al. (i.e., U.S. Patent 6,949,251). Claims 78-79 stand rejected under 35 U.S.C. § 103(a) as obvious over Kawamura et al. in view of Tanaka et al.

*The Obviousness Rejections*

The obviousness rejections are respectfully traversed.

None of the cited references, taken alone or in combination, teach or suggest particulate TCP having the properties recited in the pending claims as follows:

- (1) an average particle size within the recited range;
- (2) an average crystal size within the recited range;
- (3) a surface area with the recited range;
- (4) an ability to be densified to form an article having a minimum dimension of about 0.5 cm or greater; and
- (5) an ability to transmit 50% or more light of a particular wavelength range when densified to form an article.

*A. Properties (1), (2) and (3)*

The Office Action acknowledges that Kawamura et al. fails to teach or suggest particulate tricalcium phosphate having a particle size of 5 microns or less, but asserts that Tanaka et al. teaches that the TCP particle size should be in the range of 0.1  $\mu\text{m}$  to 200  $\mu\text{m}$  in order to optimize the dissolving rate, and that one of ordinary skill in the art would be motivated to “form the TCP articles of Kawamura et al. into particle sizes of 0.1 to 200  $\mu\text{m}$ .” Applicants respectfully traverse this assertion.

Contrary to the assertions in the Office Action, one of ordinary skill in the art would not be motivated to modify the  $\beta$ -tricalcium phosphate powder of Kawamura et al. to produce a particulate having the particle size taught by Tanaka et al. because Kawamura et al. and Tanaka et al. are directed to completely different types of biomaterials that address the problems of article strength in different ways.

Kawamura et al. is directed to a method for producing  $\beta$ -tricalcium phosphate powder, wherein the  $\beta$ -tricalcium phosphate powder is used *alone* as a raw material to produce sintered articles having high strength that can be used as bioceramics such as artificial bones. *See, e.g.*, col. 1, ll. 7-16; col. 4, ll. 34-38. Contrastingly Tanaka et al. is directed to a biomaterial comprising particulate calcium phosphate (e.g., tricalcium

phosphate) compounded with a copolymer, wherein the copolymer imparts mechanical strength to the calcium phosphate powder so as to produce a rigid biomaterial. *See, e.g.*, col. 1, ll. 5-7; col. 5, ll. 15-28 and 35-47.

One of ordinary skill in the art would appreciate that modifying the properties of the  $\beta$ -tricalcium phosphate powder of Kawamura et al. so as to achieve the particle size taught by Tanaka et al. could compromise the strength of any resulting sintered article such that it would no longer be useful as a bioceramic. Moreover, one of ordinary skill in the art would appreciate that there is no need to modify the physical properties of the tricalcium phosphate powder used by Tanaka et al. because Tanaka et al. teaches that only the particle size of the calcium phosphate material is important for the particular bioceramic application described therein.

In view of the foregoing, Applicants respectfully submit that the combination of Kawamura et al. and Tanaka et al. fails to teach or suggest properties (1)-(3) recited in the pending claims.

*B. Properties (4) and (5)*

The Office Action discounts the fourth and fifth features as being optional features that the prior art need not teach or suggest. While Applicant disagrees with this assertion, in an effort to expedite prosecution the claims have been amended to remove “can be” language and instead affirmatively recite that when the particulate TCP is densified it has the recited light transmittance, compressive strength and/or density properties. Applicant believes that these amendments make clear that the recited features are not optional features, but are required features that further characterize the properties of the particular TCP recited in the pending claims.

The Office Action asserts that even assuming that features (4) and (5) are active recitations, these features would be inherent to the teachings of Kawamura et al. and Tanaka et al. because the particulate TCP described in those references is “structurally indistinguishable” from the instantly claimed TCP. Applicants respectfully traverse this assertion.

First, as discussed above, Kawamura et al. and Tanaka et al. taken alone or in combination, fail to teach or suggest a composition comprising particulate tricalcium phosphate (TCP) having (1) an average particle size of about 5  $\mu\text{m}$  or less, (2) an average crystal size of about 250 nm or less and (3) a surface area of about 20  $\text{m}^2/\text{g}$  or greater. Because the cited references fail to disclose the recited structural features, it cannot be said that the particulate TCP recited in the pending claims is “structurally indistinguishable” from that described in Kawamura et al. when viewed in combination with Tanaka et al.

Second, nothing in Kawamura et al. and/or Tanaka et al. teaches or suggests that such the  $\beta$ -TCP material described therein, when densified, forms an article having a minimum dimension of about 0.5 cm or greater, or further will transmit about 50% or more light having a wavelength in the range of about 150 nm to about 1,000 nm as recited in the pending claims.

While Kawamura discloses that a dry powder of  $\beta$ -tricalcium phosphate having a specific surface area of 30  $\text{m}^2/\text{g}$  can be converted into an *anhydride* and then to clear crystals, such clear crystals have only 0.1 micron diameter. See col. 4, ll. 18-24. In addition, while Kawamura et al. describes sintering crystals of  $\beta$ -tricalcium phosphate to form sintered test pieces, such test pieces have a dimension of only 0.3 cm. See col. 5, ll. 17-21. Nothing suggests that the sintered test pieces of Kawamura et al. transmit light to any degree. The fact that such sintered articles are described by Kawamura et al. as exhibiting desirable strength is of no moment because strong articles are not necessarily also light transmissive.

Tanaka et al. fails to teach or suggest that the calcium phosphate powder described therein, when sintered, forms an article of any significant dimension, let alone one with a minimum dimension of 0.5 cm that further transmits light. To the contrary, Tanaka et al. teaches that the calcium phosphate powder should be sintered to form denser particles having an average particle size of 0.1 to 200  $\mu\text{m}$ . See, e.g., col. 7, l. 48, to col. 8, l. 8.

Kijima et al., Dalal et al. and Sumita each fail to cure the deficiencies of Kawamura et al. and/or Tanaka et al. None of these references teach or suggest, *inter alia*, a tricalcium phosphate powder that can be densified to form an article having a minimum dimension of about 0.5 cm or greater that is able to transmit about 50% or more light having a wavelength in the range of about 150 nm to about 1,000 nm as recited in the pending claims.

Thus, it cannot be said that Kawamura et al. viewed in combination with Tanaka et al., Kijima et al., Dalal et al. and/or Sumita, in any way teaches or suggests features (4) and (5) of the pending claims such that the claims are rendered obvious.

Finally, Applicants respectfully traverse the assertion in the Office Action that the cited references disclose a particulate tricalcium phosphate material that inherently has properties (4) and (5) of the pending claims. As set forth in the attached Declaration Under 37 C.F.R. 1.132 of Edward S. Ahn, Ph.D., a tricalcium phosphate material characterized by the structural features (1)-(3) recited in the pending claims (i.e., average crystal size, average particle size, and surface area) will not necessarily form an article having a minimum dimension of 0.5 cm that further transmits 50% or more of light having a wavelength in the range of about 150 nm to about 1,000 nm. Particulate tricalcium phosphate powders that form such articles having light transmittance properties must have the recited structural features in the proper ratio, and must further be free of chemical impurities (e.g., calcium phosphate impurities) and/or phase impurities (e.g., undesirable ratios of  $\alpha$ -TCP and  $\beta$ -TCP) that adversely affect the microstructure of the ceramic and cause significant flaw sizes that prevent particulate TCP from being able to be densified to form an article that is permeable to light. It is simply not the case that a reference disclosing features (1)-(3) of the pending claims inherently also discloses features (4) and (5).

In view of the foregoing, Applicants respectfully submit that the obviousness rejections are improper and should be withdrawn.

*New claims 83-85*

New claims 83-85 are directed to a composition comprising particulate tricalcium phosphate (TCP) having an average particle size of about 5  $\mu\text{m}$  or less, an average crystal size of about 250 nm or less and a surface area of about 20  $\text{m}^2/\text{g}$  or greater, wherein the particulate TCP is produced using a wet chemical approach, and wherein when the particulate TCP is densified to form an article having a minimum dimension of about 0.5 cm or greater the article has a density that is 90% of the theoretical density or greater. Kawamura et al. fails to teach or suggest a particulate tricalcium phosphate composition produced using a wet chemical approach having the average particle size, average crystal size and surface area recited in pending claims 83-85.

As discussed previously in response to the Office Action dated March 12, 2008, Kawamura et al. is directed to a  $\beta$ -tricalcium phosphate prepared by a *mechanochemical* process involving preparing a slurry of hydrogen calcium phosphate and calcium carbonate powders in water and then subjecting that slurry to attrition (e.g., using a ball mill). *See* Abstract; col. 2, ll. 31-49; col. 3, ll. 29-43, and Example 1. Kawamura et al. contrasts this mechanochemical approach from a wet chemical approach, which it describes as suffering numerous disadvantages including low purity and poor crystal formation. *See* col. 1, ll. 46, to col. 2, ll. 12.

The deficiencies of Kawamura et al. are not cured by Tanaka et al., Kijima et al., Dalal et al. and/or Sumita because none of these references teach or suggest a particulate tricalcium phosphate composition produced using a wet chemical approach having the average particle size, average crystal size and surface area recited in pending claims 83-85.

In view of the foregoing, Applicants respectfully submit that claims 83-85 are neither anticipated nor rendered obvious by the cited references.

### *Conclusion*

Applicants respectfully submit that the patent application is in condition for allowance. If, in the opinion of the Examiner, a telephone conference would expedite the prosecution of the subject application, the Examiner is invited to call the undersigned attorney.

Respectfully submitted,



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